

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

11 CIV 2401

PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC.,  
PURDUE PHARMACEUTICALS L.P.,  
and RHODES TECHNOLOGIES,

Plaintiffs,

v.

RANBAXY INC.,  
RANBAXY PHARMACEUTICALS INC.,  
and RANBAXY LABORATORIES LTD.,

Defendants.

C.A. No. \_\_\_\_\_



**COMPLAINT**

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue  
Pharmaceuticals L.P., and Rhodes Technologies for their Complaint herein, aver as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of  
the United States, Title 35, United States Code.

**THE PARTIES: PLAINTIFFS**

2. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership  
organized and existing under the laws of the State of Delaware, having a place of business at One  
Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an  
owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs  
19-21 below. Purdue Pharma is also the holder of New Drug Application ("NDA") No. 022272

for the controlled-release oxycodone pain-relief medication OxyContin<sup>®</sup>, and is involved in the sales of OxyContin<sup>®</sup> in the United States.

3. Plaintiff The P.F. Laboratories, Inc. (“P.F. Labs”) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 19-21 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

4. Plaintiff Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 19-21 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

5. Plaintiff Rhodes Technologies (“Rhodes”) is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 19-21 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

6. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are associated companies.

**THE PARTIES: DEFENDANTS**

7. Upon information and belief, Defendant Ranbaxy Inc. (“RI”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

8. Upon information and belief, RI is registered as a Foreign Business Corporation by the New York State Department of State, Division of Corporations and lists Corporation Service Company, 80 State Street, Albany, NY 12207-2543 as its registered agent.

9. Upon information and belief, Defendant Ranbaxy Pharmaceuticals Inc. (“RPI”) is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257.

10. Upon information and belief, RPI is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration No. 025942). The Registration has an active status and is valid through February 29, 2012.

11. Upon information and belief, Defendant Ranbaxy Laboratories Ltd. (“RLL”) is a corporation organized under the laws of India, having its principal place of business at Plot No. 90, Sector 32, Gurgaon – 122 001 (Haryana), India.

12. Upon information and belief, RI is a wholly owned subsidiary of RLL.

13. Upon information and belief, RPI is a wholly owned subsidiary of RLL.

14. Upon information and belief, the acts of RLL complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of RPI and RI.

15. RI, RPI, and RLL are referred hereinafter collectively as “Ranbaxy.”

**JURISDICTION AND VENUE**

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

17. This Court has personal jurisdiction over Ranbaxy because, *inter alia*, Ranbaxy has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Ranbaxy does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Ranbaxy engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States, this State, and this Judicial District specifically. Ranbaxy has previously consented to personal jurisdiction in this Judicial District in patent litigation concerning an earlier Abbreviated New Drug Application (“ANDA”) that Ranbaxy submitted to the FDA that was also directed to generic oxycodone hydrochloride extended release tablets. *See Purdue Pharma L.P. et al. v. Ranbaxy Inc.*, No. 10-civ-3734 (SHS) (S.D.N.Y. May 5, 2010). Further, this Court has personal jurisdiction over Ranbaxy because RPI is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. This Court also has personal jurisdiction over Ranbaxy because RI is registered as a Foreign Business Corporation by the New York State Department of State, Division of Corporations. In addition, upon information and belief, Ranbaxy is actively preparing to make the proposed generic copies of OxyContin<sup>®</sup> that are the subject of ANDA No. 202427, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

18. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

**THE PATENTS IN SUIT**

19. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,799 entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’799 patent”), including all right to sue and to recover for past infringement thereof, which patent is listed in FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 022272. A copy of the ’799 patent is attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

20. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,800 entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’800 patent”), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 022272. A copy of the ’800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

21. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,683,072 entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’072 patent”), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 022272. A copy of the ’072 patent is

attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

**DEFENDANTS' ANDA**

22. Upon information and belief, Ranbaxy submitted ANDA No. 202427 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets, 30 mg, 40 mg, 60 mg, and 80 mg, (“proposed generic copies of OxyContin<sup>®</sup>”) based on the Reference Listed Drug (“RLD”) OxyContin<sup>®</sup>, which is the subject of approved NDA No. 022272, before the expiration of the ’799, ’800, and ’072 patents.

23. Upon information and belief, Ranbaxy’s ANDA No. 202427 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that “no valid, enforceable claim” of the ’799, ’800, and ’072 patents listed in the FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 022272, “will be infringed by the manufacture, importation, use, sale, or offer for sale” of its proposed generic copies of OxyContin<sup>®</sup>.

24. In letters dated February 24, 2011 addressed to Plaintiff Purdue Pharma, The University of Texas System, and Grünenthal GmbH, and received by Plaintiff Purdue Pharma on February 25, 2011, Ranbaxy provided “Notice” with respect to its proposed generic copies of OxyContin<sup>®</sup> and the ’799, ’800, and ’072 patents under 21 U.S.C. § 355(j)(2)(B).

25. Ranbaxy’s submission of its ANDA was an act of infringement of the ’799, ’800, and ’072 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Ranbaxy’s proposed generic copies of OxyContin<sup>®</sup> are covered by one or more claims of the ’799, ’800, and ’072 patents.

27. Upon information and belief, Ranbaxy's commercial manufacture, use, sale, and/or offer for sale of its proposed generic copies of OxyContin<sup>®</sup> would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '799, '800, and '072 patents.

28. Upon information and belief, Ranbaxy has been aware of the existence of the '799, '800, and '072 patents, and has no reasonable basis for believing that its proposed generic copies of OxyContin<sup>®</sup> will not infringe the '799, '800, and '072 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

29. The acts of infringement by Ranbaxy set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Ranbaxy has infringed the '799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of its proposed generic copies of OxyContin<sup>®</sup> described in ANDA No. 202427 would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, and '072 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202427, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the dates of expiration of the '799, '800, and '072 patents plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Ranbaxy, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their



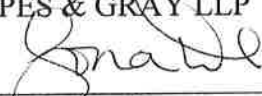
successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '799, '800, and '072 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: April 7, 2011

ROPES & GRAY LLP



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Pablo D. Hendler

Sona De

1211 Avenue of the Americas

New York, NY 10036

(212) 596-9000

[pablo.hendler@ropesgray.com](mailto:pablo.hendler@ropesgray.com)

[sona.de@ropesgray.com](mailto:sona.de@ropesgray.com)

Robert J. Goldman

1900 University Avenue, 6th Floor

East Palo Alto, CA 94303

(650) 617-4000

[robert.goldman@ropesgray.com](mailto:robert.goldman@ropesgray.com)

*Attorneys for Plaintiffs*

*Purdue Pharma L.P.,*

*The P.F. Laboratories, Inc.,*

*Purdue Pharmaceuticals L.P., and*

*Rhodes Technologies*